

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-44

☐ Other ☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base Option Period Number 2

Title of Work Assignment/SF Site Name

2016 Conference

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

E. 2

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/01/2015 To 10/31/2016

Comments:

Support to the 2016 US EPA International Decontamination Research and Development Conference



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO

(Max 2)



Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

11/01/2013 To 10/31/2016

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee

LOE:

Cumulative Approved:

Cost/Fee

LOE:

Work Assignment Manager Name Lukas Oudejans

Branch/Mail Code:

Phone Number: 919-541-2973

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

(Signature)

(Date)

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-44

TITLE: Support to the 2016 US EPA International Decontamination Research and Development Conference

Specify Section & Paragraph SOW: E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: *CO award to 10/31/16*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) for administrative and technical support to the 2016 US EPA International Decontamination Research and Development Conference, hosted by EPA's National Homeland Security Research Center (NHSRC).

The desired goals of the conference are the following:

- To bring together researchers, responders, U.S. and international government and private stakeholders in CBR remediation and recovery preparedness;
- To facilitate the exchange of information on scientific endeavors, including applied research, field demonstrations, guidance and tool development and field applications related to CBR remediation issues; and,
- To demonstrate the connection between basic or fundamental decontamination research and applied research, as well as applied research and effective field application.

The work assignment has three major components: (1) the preparation and (2) implementation of a three day conference to take place on November 1-3, 2016, at the EPA RTP campus in North Carolina; (3) the preparation of a post-conference report that compiles the abstracts and presentations along with an executive summary of the conference. This work assignment includes the following major deliverables:

1. Assistance and coordination with a three day conference as noted in the tasks.
2. Administrative and Technical support for the three day Decontamination R&D Conference.
3. Assistance with plenary speaker and up to three other outside participants.
4. Post-conference summary report.

This WA only identifies tasks leading up to the conference and does not include tasks to be conducted during the conference or other post conference tasks.

II. BACKGROUND

Since 2005, NHSRC has organized and hosted an international conference on decontamination research and development. Decontamination is one of the critical challenges that the United States and EPA would face in recovering from a major chemical, biological, or radiological incident.

The conference is designed to facilitate presentation, discussion, and further collaboration on research and development focused on an all-hazards approach to cleaning up contaminated buildings (both interior and exterior), infrastructure, and other areas/materials. The conference continues to focus strongly on matters involving chemical, biological, and radiological (CBR) threat agents but also include “all hazards’ elements.

Topics of interest for this conference include:

- New research data, or field activities and large scale demonstrations related to the detection and decontamination of biological (including agricultural threat agents and biotoxins), chemical, and radiological threat agents in indoor (in facilities) or outdoor areas/materials
- Cross cutting topics related to restoration including: clean-up levels/risk assessment, exposure assessment, sampling/analysis of threat agents, fate/transport/containment, material compatibility with decontamination processes, tool and guidance development, waste management of threat agent-contaminated materials, water/wastewater decontamination, and systems approach to response and regulatory issues.

Invitees include persons involved in CBR remediation and recovery research, individuals such as EPA On-Scene Coordinators who conduct remediation activities, people involved in setting policy related to CBR decontamination in the U.S. and abroad, as well as individuals from academia and industry.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference.

Task 3: PRE-CONFERENCE PREPARATION

Task 3.1. Conference Abstract Collection:

The contractor shall setup an email account to receive abstracts as submitted by participants. The email address shall reflect the intended purpose of this conference. The Contractor shall receive conference abstracts following the initial call for abstracts by the conference organizers.

The Contractor shall compile received abstract titles and prepare a spreadsheet to facilitate EPA review of abstracts and placement in the conference program following acceptance by EPA of the presentation.

Task 3.2. Pre-registering Conference Participants:

The Contractor shall setup a conference registration website for all participants. The Contractor shall include in the on-line pre-registration information a list of local hotels and other pertinent logistical information. The registration process shall include obtaining information whether the registrant is a United States citizen or permanent resident, identification of research area (down selected from

prepopulated list of up to 10 topics), selection of preferred presentation mode (oral vs poster presentation), and whether the contact information (name and affiliation) can be made available to (a) only other registrants of the conference or (b) the general public as part of the post-conference report. Upon receipt of a registration request, the Contractor shall determine if the registrant belongs to the list of invitees as provided by the EPA WAM. If not, the Contractor shall contact the WAM on whether to accept or decline the registration. The Contractor shall confirm a successful registration with the registrant. The EPA WAM will inform a registrant if the registration cannot be accepted.

The Contractor shall provide a spreadsheet of pre-registrants 4 weeks prior to the conference, and again beginning each week thereafter until the start of the conference, unless there were no new pre-registrants added during that period.

The Contractor shall secure a block of rooms at a hotel near the EPA RTP Campus at the government rate. The Contractor shall inquire whether transportation to the EPA RTP Campus can be accommodated by the selected hotel.

Task 3.3. Other Pre-Meeting Logistical Activities (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support):

The Contractor shall, when given a list of potential speakers, moderators, key audience members and other audience categories, secure release forms for presentations by all speakers for both upload onto an ftp-like server and for publication in the conference report, obtain their appropriate power point presentations and organize these presentations in an appropriate manner to be ready to load onto EPA computers at the conference. The Contractor will confirm moderator participation in cooperation with the WAM. The Contractor shall also provide other necessary logistical support for presenters and attendees including directions to the conference and coordination of presentation materials.

The Contractor shall coordinate with the EPA AV support personnel in RTP in advance of the conference to ensure that proper AV equipment is available (microphones, laptops and projectors). EPA has secured meeting space at the EPA facilities on the RTP, NC campus. The Contractor shall serve as the lead point of contact to insure the adequate flow of all activities on the days of the conference and coordinate the speakers and overall participation of other representatives. The Contractor shall include arrangements for a webinar version of the conference (one room only).

The Contractor shall be available for on-site registration as necessary, provide any copies of EPA relevant meeting material and allow sufficient space at the entry table for speakers and participants to leave relevant information for pick-up at the time of on-site registration. The Contractor shall coordinate registration near the main meeting room.

Task 3.4. Preparing Conference Materials:

The Contractor shall prepare information materials in a conference Information Packet. The packet shall include announcements and a final conference agenda. The Contractor shall provide a list of overall participants and presenters, their contact information, and Bios of presenters. The Contractor shall include this information in a Conference Information Packet and make these packets available in sufficient numbers to provide each participant with a packet at the time of on-site registration.

TASK 4: CONFERENCE INVITED SPEAKER TRAVEL

Task 4.1. Invited Speaker Travel:

The Contractor shall identify 1 international and up to 3 domestic scientists to be invited speakers at the conference. The Contractor shall then coordinate logistics and pay for their travel. The Contractor shall anticipate that the speakers will attend the entire Conference.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software e.g., MS Office 2010 (or later) spreadsheets and documents.

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Work, Staffing Plan	20 days after award
Task 3. List of Abstracts List of Registrants Conference Information Packets	September 1, 2016 4 weeks prior to conference and weekly up to conference date October 31, 2016
Task 4. List of Invited Speakers	September 1, 2016

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Lukas Oudejans
U.S. EPA, ORD/NHSRC
109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2973
oudejans.lukas@epa.gov

Alternate WAM:

Tanya Medley
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109 TW Alexander Dr.
Research Triangle Park, NC 27711
919-541-2336
medley.tanya@epa.gov

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-44			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 2			Title of Work Assignment/SF Site Name US EPA International Decontami			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval						Period of Performance From 11/01/2015 To 10/31/2016			
Comments:									
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.									
SFO <input type="checkbox"/> (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee: \$0.00		LOE: 0					
11/01/2013 To 10/31/2016									
This Action:		\$33,328.00		371					
Total:		\$33,328.00		371					
Work Plan / Cost Estimate Approvals									
Contractor WP Dated: 06/15/2016		Cost/Fee \$33,328.00		LOE: 371					
Cumulative Approved:		Cost/Fee \$33,328.00		LOE: 371					
Work Assignment Manager Name Lukas Oudejans <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-2973 FAX Number:			
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name William Yates <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:			

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-46				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base <input checked="" type="checkbox"/> Option Period Number			Title of Work Assignment/SF Site Name				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 11/12/2015 To 10/31/2016				
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
11/01/2013 To 10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name Andrew Hotchkiss <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number 919-541-4164 FAX Number:			
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Adam Meier <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107			

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-46

TITLE: Literature search and analysis of available epidemiological data available for human health effects observed due to *in utero* exposures to environmental pollutants.

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: CO Award thru 10/31/2016

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for conducting literature searches and subsequent analyses of human epidemiological studies that have observed health effects due to in utero exposure to environmental pollutants. The development of project will include the development of literature searches, systematic review (including risk of bias) evidence tables, identification of biomarkers of exposure and analyses of available NHANES data, derivation of points of departure (PODs) for select studies, characterization of the exposure distribution for women of reproductive age, evaluation of mechanistic data to provide insight into possible adverse outcome pathways (AOPs).

II. BACKGROUND

The importance of *in utero* exposures relative to environmental pollutants has resulted in numerous epidemiological studies characterizing the association between this critical time window of exposure and health effects resulting in later life. Based upon a brief literature search, epidemiological studies have characterized relationships between health effects and environmental pollutants including polybrominated diphenyl ether (Chen et al., 2013; Eskenazi, et al., 2013;), polyaromatic hydrocarbons (PAHs; Perera et al., 2012; 2009), arsenic (Graziano et al., 2014; Nadeau et al., 2014; Recio-Vega et al., 2014; Steinmaus et al., 2014), lead (Nye et al., 2014), methylmercury (Yorifuji, et al., 2014; Zeilmaker et al., 2011; Ryan, 2008), perfluorooctanoic acid (Chen et al., 2013;) and organochlorines (Vested et al., 2014; Eskenazi, et al., 2008). Of the many health effects associated with in utero exposures, developmental neurotoxicity appears to result from many environmental pollutants and this brief review indicates there may exist sufficient data for a number of environmental pollutants to focus on the decrements in IQ. However, based upon the initial literature search other endpoints may be selected to compare across environmental pollutants. Current human health assessments for many of the environmental pollutants identified here have yet to fully evaluate effects associated with in utero exposures. A focused effort on specific health effects (i.e., developmental neurotoxicity) across a group of compounds may provide insight and methodologies for future risk assessments. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In conducting the literature review, subsequent analyses, and documents characterizing the state of the science and analyses, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)

- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of analyses and documents characterizing the state of the science on health effects observed in human populations resulting from in utero exposures to environmental pollutants. Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/O 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)*"; "*EPA Requirements for Quality Assurance*

Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Literature search for identification of human epidemiological literature of health effects due to in utero exposure to environmental pollutants

Prior to initiation of Task 3, a broad literature and internet search should be conducted to identify projects and/or reports describing similar efforts to Tasks 3-6 of this work assignment. The findings of this search should be provided to the WAM for concurrence to conduct the remaining efforts described in Task 3. The objective of this task is conduct complete literature searches to identify human epidemiological data and toxicological data (i.e., animal studies) that have observed human health effects in later life due to exposure to environmental pollutants in utero. Based upon the environmental pollutants there may be a range of available data. At this point, literature searches shall be inclusive of cancer and non-cancer effects associated with in utero exposures to environmental pollutants. The literature search strategy shall be documented and characterize the numerical results of the search. Based upon this literature search, data should be summarized in Hazard ID Summary tables (i.e., similar to tables developed for the inorganic arsenic human health risk assessment) for review and subsequent direction of this effort (i.e., selection of health effect endpoints to further characterize). When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

- 3.1 Literature Search and Hazard ID Summary Tables and Summary Report: The Contractor shall assist EPA in preparing revised versions of literature search and Hazard ID Summary tables based upon reviewer comments. A summary report will be drafted to characterize the available hazard information (human and animal) for environmental pollutants identified in the literature search and to delineate a decision for the selection of health effect(s) / endpoint(s) for further analyses in this PWS. Comparability of data across relevant studies for the selected endpoints should be a key consideration in the selection of the health effect(s) / endpoint(s). Based upon the literature search results, PECO statements will be developed to guide subsequent analyses. Reviewers may include, but are not limited to, internal Agency and interagency participants.

Deliverables:

Literature search product and documentation

Hazard ID Summary tables

Summary report to document the available hazard information for identified chemicals, selection of health effects and develop PECO statement(s) for further analysis (based upon technical direction)

Task 4: Systematic Review and Derivation of Points of Departure (PODs)

The objective of this task is to conduct a systematic review of the available literature for the selected endpoint(s) to determine the most appropriate studies to derive a point of departure(s) that could be used for future derivation of toxicity values. This task will be highly dependent upon the available literature and selection of endpoint(s) / health effects to characterize across a group of environmental pollutants from Task 3. The systematic review will be conducted on multiple endpoints / health effects identified in Task 3, but only

endpoint(s) with sufficient data to assess causality. Technical direction will be provided by the WAM as to selection of endpoints and priority for conducting the systematic review. The systematic review will be guided by the PECO statements developed in Task 3 and be limited in scope. The protocol for the systematic review (including risk of bias) will be documented prior to evaluating studies. Although protocol development is outlined in Task 4, there will exist overlap with Task 3 which will require partial development of the protocols for completion of Task 3. Based upon the results from the systematic review, the best available studies for each pollutant will be utilized for derivation of potential PODs.

Specific requirements of this task:

4.1 Systematic Review and Dose-Response Analyses

Deliverables:

Systematic Review Protocol

Risk of bias evaluations

Summary report of systematic review of selected studies

POD derivations

Summary report of POD derivations

Task 5: Efforts related Exposure Characterization

The objective of this task is to characterize exposure to the identified environmental pollutants using existing public databases. The National Health and Nutrition Examination Survey (NHANES) routinely collects biomarkers of exposure (e.g., blood and urine levels) for well-known environmental pollutants. For the environmental pollutants identified in Task 3, for which there is sufficient epidemiological data to suggest a potential human health hazards, NHANES and other publicly available databases will be searched to identify biomarkers of exposure. Based upon the available data the goal of this task will be to characterize the distribution of exposure to women of reproductive age, however this task will be limited by the available data. The approach and boundaries for identification, data retrieval, and exposure characterization will be dependent upon the environmental pollutants identified in Task 3. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

- 5.1 Exposure Characterization: The Contractor shall assist EPA in drafting documents to characterize the exposure profile within United States populations and the retrieval of exposure information from publicly available databases

Deliverables:

General exposure profiles for US populations for each environmental pollutant (estimated 10)

Exposure characterization based upon exposure biomarkers from publicly available databases for women of reproductive age

Task 6: Efforts related to development of Adverse Outcome Pathways (AOPs)

The objective of this task is to assist EPA in evaluating the available mechanistic information for the endpoint(s) selected in Task 3. Based upon the endpoint selected in Task 3, the contractor shall conduct a complete literature search for mechanistic information that may support the development of AOPs for the

selected endpoint(s). The available information should be arranged by components of AOP analysis (i.e., molecular initiating event, etc.). Based upon the endpoint(s) selected a review of available proposed AOPs or modes of action (MOA) should also be evaluated. Based upon the available information the WAM will provide technical direction as to the feasibility of developing an AOP for the selected endpoints.

Specific requirements of this task:

- 6.1 AOP Evaluation and Analyses: The contractor shall develop a summary report characterizing the available mechanistic information available for development of AOPs for the selected endpoint. Further analyses may be required to document and develop an AOP analyses.

Deliverable:

Summary report of available mechanistic information

Review of available AOP hypotheses

Development of a proposed AOP(s)

Task 7: Characterization of Risk Estimation Methodology and Potential Future Directions

The objective of this task is to assist EPA in characterize the available / current approaches for hazard identification and dose-response analysis of developmental, reproductive, and health effects occurring later in life due to in utero exposures. A report shall be developed to characterize the current approaches by EPA and other risk assessment organizations. Additionally, considering the unique data sets available for in utero exposure, reproductive, and developmental studies the report will explore the development of new risk assessment methodological approaches to adequately account for health effects reported within the study types listed in this task. The advantages and disadvantages of current and proposed future approaches shall be characterized in this report.

Specific requirements of this task:

- 7.1 Risk assessment approaches: The contractor shall develop a summary report characterizing current and possible future approaches for hazard identification and dose-response analysis for developmental, reproductive, and health effects resulting from in utero exposure.

Deliverable:

Summary report for current and future risk assessment methodologies for specific types of studies

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.d), *.out, *.opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3. Literature Search for Epi Literature from In Utero Exposures	
Task 3.1 – Literature Search and Hazard ID	
• Literature Search Product and Documentation	3 weeks from completion of Task 2
• Hazard ID Summary Tables	5 weeks from completion of Task 2
• Summary Report for Hazard ID	10 weeks from completion of Task 2
Task 4. Systematic Review and POD Derivation	
Task 4.1 – Systematic Review and Dose-Response Analyses	
• Systematic Review Protocol	3 weeks from completion of Task 3
• Risk of Bias Evaluations	5 weeks from completion of Task 3
• Summary Report Sys Rev/ Selected Studies	8 weeks from completion of Task 3
• POD Derivations	12 weeks from completion of Task 3
• Summary Report PODs	14 weeks from completion of Task 3
Task 5. Efforts Related to Exposure Characterization	
Task 5.1 – Exposure Characterization	
• General Exposure Profiles for Selected Pollutants	3 weeks from completion of Task 3 (can be conducted in parallel with ROB evaluations)
• Exposure Characterization Publicly Available Biomarker Data	8 weeks from completion of Task 3 (can be conducted in parallel with ROB evaluations)
Task 6. Efforts related to AOPs	
Task 6.1 – AOP Evaluation and Analyses	
• Summary Report of Available Mechanistic Info for Selected Endpoint(s)	3 weeks from completion of Task 5
• Review of Available AOPs	6 weeks from completion of Task 5
• Development of Proposed AOPs	10 weeks from completion of Task 5
Task 7. Characterization of Risk Estimation Methodology and Potential Future Directions	
Task 7.1 – <u>Risk assessment approaches</u>	
Summary Report of Available Mechanistic Info for Selected Endpoint(s)	3 weeks from completion of Task 5
• Summary report for current and future risk assessment methodologies for specific types of studies	

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

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Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

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IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Managers (WAMs):

Andrew Hotchkiss, PhD
919-541-4164
Hotchkiss.Andrew@epamail.epa.gov

Ellen Kirrane, PhD
919-541-1340
Kirrane.Ellen@epamail.epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

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INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

- 1.) Bibliographic identification of the study.

Study Identifiers:

Author(s):

Title:

Study Citation:

Storage location (e.g., library, facility archive, personal archive):

- 2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
- 3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
- 4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
- 5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
- 6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-46

☐ Other ☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base Option Period Number 2

Title of Work Assignment/SF Site Name

In utero exposures

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/12/2015 To 10/31/2016

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO

(Max 2)



Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

11/01/2013 To 10/31/2016

Cost/Fee: \$0.00

LOE: 0

This Action:

\$123,418.00

1,343

Total:

\$123,418.00

1,343

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

12/02/2015

Cost/Fee

\$123,418.00

LOE:

1,343

Cumulative Approved:

Cost/Fee

\$123,418.00

LOE:

1,343

Work Assignment Manager Name Andrew Hotchkiss

Branch/Mail Code:

Phone Number: 919-541-4164

FAX Number:

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

Contracting Official Name

(Signature)

(Date)

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-46	
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001	
Contract Number EP-C-14-001		Contract Period 11/01/2013 To 10/31/2017		Title of Work Assignment/SF Site Name			
		Base Option Period Number 2		In Utero			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW			
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval				Period of Performance From 11/12/2015 To 10/31/2016			
Comments:							
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund							
SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.							
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents) Site/Project (Max 8) Cost Org/Code
1							
2							
3							
4							
5							
Authorized Work Assignment Ceiling							
Contract Period: 11/01/2013 To 10/31/2017		Cost/Fee:		LOE:			
This Action:							
Total:							
Work Plan / Cost Estimate Approvals							
Contractor WP Dated:				Cost/Fee		LOE:	
Cumulative Approved:				Cost/Fee		LOE:	
Work Assignment Manager Name Andrew Hotchkiss						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number: 919-541-4164	
						FAX Number:	
Project Officer Name Melissa Revely-Wilson						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number: 919-541-0207	
						FAX Number:	
Other Agency Official Name						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number:	
						FAX Number:	
Contracting Official Name William Yates						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number: 513-487-2055	
						FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-46

TITLE: Literature search and analysis of available epidemiological data available for human health effects observed due to in utero exposures to environmental pollutants.

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: CO Award thru 10/31/2016

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for conducting literature searches and subsequent analyses of human epidemiological studies that have observed health effects due to in utero exposure to environmental pollutants. The development of project will include the development of literature searches, systematic review (including risk of bias) evidence tables, identification of biomarkers of exposure and analyses of available NHANES data, derivation of points of departure (PODs) for select studies, characterization of the exposure distribution for women of reproductive age, evaluation of mechanistic data to provide insight into possible adverse outcome pathways (AOPs).

II. BACKGROUND

The importance of in utero exposures relative to environmental pollutants has resulted in numerous epidemiological studies characterizing the association between this critical time window of exposure and health effects resulting in later life. Based upon a brief literature search, epidemiological studies have characterized relationships between health effects and environmental pollutants including polybrominated diphenyl ether (Chen et al., 2013; Eskenazi, et al., 2013;), polyaromatic hydrocarbons (PAHs; Perera et al., 2012; 2009), arsenic (Graziano et al., 2014; Nadeau et al., 2014; Recio-Vega et al., 2014; Steinmaus et al., 2014), lead (Nye et al., 2014), methylmercury (Yorifuji, et al., 2014; Zeilmaker et al., 2011; Ryan, 2008), perfluorooctanoic acid (Chen et al., 2013;) and organochlorines (Vested et al., 2014; Eskenazi, et al., 2008). Of the many health effects associated with in utero exposures, developmental neurotoxicity appears to result from many environmental pollutants and this brief review indicates there may exist sufficient data for a number of environmental pollutants to focus on the decrements in IQ. However, based upon the initial literature search other endpoints may be selected to compare across environmental pollutants. Current human health assessments for many of the environmental pollutants identified here have yet to fully evaluate effects associated with in utero exposures. A focused effort on specific health effects (i.e., developmental neurotoxicity) across a group of compounds may provide insight and methodologies for future risk assessments. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In conducting the literature review, subsequent analyses, and documents characterizing the state of the science and analyses, the Contractor shall follow, as applicable, the following EPA guidance documents:

- A Review of the Reference Dose and Reference Concentration Processes (U.S. EPA, 2002)
- Guidelines for Neurotoxicity Risk Assessment (U.S. EPA, 1998)

- Guidelines for Reproductive Toxicity Risk Assessment (U.S. EPA, 1996)
- Guidelines for Developmental Toxicity Risk Assessment (U.S. EPA, 1991)
- Guidelines for Mutagenicity Risk Assessment (U.S. EPA, 1986)
- Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (U.S. EPA, 1994)
- Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988)
- Guidelines for the Health Risk Assessment of Chemical Mixtures (U.S. EPA, 1986)
- Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures (U.S. EPA, 2000)
- A Framework for Assessing Health Risks of Environmental Exposures to Children (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of analyses and documents characterizing the state of the science on health effects observed in human populations resulting from in utero exposures to environmental pollutants. Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance

Project Plans (QAR-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Literature search for identification of human epidemiological literature of health effects due to in utero exposure to environmental pollutants

Prior to initiation of Task 3, a broad literature and internet search should be conducted to identify projects and/or reports describing similar efforts to Tasks 3-6 of this work assignment. The findings of this search should be provided to the WAM for concurrence to conduct the remaining efforts described in Task 3. The objective of this task is conduct complete literature searches to identify human epidemiological data and toxicological data (i.e., animal studies) that have observed human health effects in later life due to exposure to environmental pollutants in utero. Based upon the environmental pollutants there may be a range of available data. At this point, literature searches shall be inclusive of cancer and non-cancer effects associated with in utero exposures to environmental pollutants. The literature search strategy shall be documented and characterize the numerical results of the search. Based upon this literature search, data should be summarized in Hazard ID Summary tables (i.e., similar to tables developed for the inorganic arsenic human health risk assessment) for review and subsequent direction of this effort (i.e., selection of health effect endpoints to further characterize). When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

- 3.1 Literature Search and Hazard ID Summary Tables and Summary Report: The Contractor shall assist EPA in preparing revised versions of literature search and Hazard ID Summary tables based upon reviewer comments. A summary report will be drafted to characterize the available hazard information (human and animal) for environmental pollutants identified in the literature search and to delineate a decision for the selection of health effect(s) / endpoint(s) for further analyses in this PWS. Comparability of data across relevant studies for the selected endpoints should be a key consideration in the selection of the health effect(s) / endpoint(s). Based upon the literature search results, PECO statements will be developed to guide subsequent analyses. Reviewers may include, but are not limited to, internal Agency and interagency participants.

Deliverables:

Literature search product and documentation

Hazard ID Summary tables

Summary report to document the available hazard information for identified chemicals, selection of health effects and develop PECO (population exposure comparison outcome) statement(s) for further analysis (based upon technical direction)

Task 4: Systematic Review Data Extraction, Development of Summary Figures

The objective of this task is to generate the data needed to conduct the analyses needed for a systematic review of the available literature for the selected endpoint(s) to determine the most appropriate studies for inclusion in the analysis. This task will be highly dependent upon the available literature and selection of endpoint(s) / health effects to characterize across a group of environmental pollutants from Task 3. The systematic review

will be conducted on multiple endpoints / health effects identified in Task 3, but only endpoint(s) with sufficient data to support a robust analysis. Technical direction will be provided by the WAM as to selection of endpoints and priority for conducting the systematic review. The systematic review will be guided by the PECO statements developed in Task 3 and be limited in scope. The protocol for the systematic review (including risk of bias) will be documented prior to evaluating studies. Although protocol development is outlined in Task 4, there will exist overlap with Task 3 which will require partial development of the protocols for completion of Task 3.

EPA will provide technical direction to finalize and define specific health endpoints for analysis. Technical direction will include but not be limited to providing literature search terms for consideration and refinement of the final endpoint definition. Based on the endpoints identified by EPA (i.e. hypospadias, asthma, cognitive effects, and birth outcomes) the Contractor shall screen and characterize the studies identified through the application of the literature search methodology in order complete and/or identify the set of studies to be included in the analysis. At a minimum, eligible studies shall evaluate NHANES chemicals, use a biomarker in their exposure assessments and examine in utero exposures. Lists of additional informative studies may be compiled as needed.

The Contractor shall extract relevant data from the identified set of studies for each of the endpoint groupings. Data shall include but not be limited to the following:

- (1) Measure of effect or association;
- (2) Chemical
- (3) Biomarker
- (4) Outcome
- (5) Covariates considered (e.g. age, sex)
- (6) Dose-response analysis (Yes/No)
- (7) Other study details (e.g. population, comparison, study design, outcome ascertainment)

The Contractor shall assist EPA in efforts to standardize or transform data so that it can be plotted and overlaid with NHANES exposure distribution data (see Task 5).

Specific requirements of this task:

- 4.1 Systematic Review Methods Report: The Contractor shall develop a report summarizing the methods applied in the project overall and in the hypospadias pilot project.
- 4.2 Revise report: In Consultation with EPA, the Contractor shall revise and frame findings from the report so that they is suitable for publication in a peer-reviewed journal. The Contractor shall provide written outline(s) to the WAM for review prior to writing the report. The Contractor shall participate in telephone meetings as needed with EPA staff.

Deliverables:

Systematic Review Methods Report

Summary report of systematic review of selected studies (i.e. hypospadias)

Task 5: Efforts related Exposure Characterization

The objective of this task is to characterize exposure to the identified environmental pollutants using existing public databases. The National Health and Nutrition Examination Survey (NHANES) routinely collects biomarkers of exposure (e.g., blood and urine levels) for well-known environmental pollutants. For the environmental pollutants identified in Task 3, for which there is sufficient epidemiological data to suggest a potential human health hazards, NHANES and other publicly available databases will be searched to identify biomarkers of exposure. Based upon the available data the goal of this task will be to characterize the distribution of exposure to women of reproductive age, however this task will be limited by the available data. The approach and boundaries for identification, data retrieval, and exposure characterization will be dependent upon the environmental pollutants identified in Task 3. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

- 5.1 Exposure Characterization: The Contractor shall assist EPA in drafting documents to characterize the exposure profile within United States populations and the retrieval of exposure information from publicly available databases

Deliverables:

General exposure profiles for US populations for each environmental pollutant (estimated 10)

Exposure characterization based upon exposure biomarkers from publicly available databases for women of reproductive age

Task 6: Efforts related to evaluation of toxicological data and development of existing Adverse Outcome Pathways (AOPs) available in the peer-reviewed literature

The objective of this task is to assist EPA in evaluating the available mechanistic information for the endpoint(s) selected in Task 3. Based upon the endpoint selected in Task 3, the contractor shall conduct a complete literature search for toxicological and mechanistic information for the selected endpoint(s). The available information should be arranged by components of AOP analysis (i.e., molecular initiating event, etc.). Based upon the endpoint(s) selected a review of available proposed AOPs or modes of action (MOA) should also be evaluated. Based upon the available information the WAM will provide technical direction as to the feasibility of developing an AOP for the selected endpoints.

Specific requirements of this task:

- 6.1 Evaluation and Analyses: The contractor shall develop a summary report characterizing the available toxicological and mechanistic information available for development of AOPs for the selected endpoint. Further analyses may be required to document and develop an AOP analyses.

Deliverable:

Summary report of available toxicological and mechanistic information

Review of available AOP hypotheses

Task 7: Characterization of Risk Estimation Methodology and Potential Future Directions

The objective of this task is to assist EPA in characterize the available / current approaches for hazard identification and dose-response analysis of developmental, reproductive, and health effects occurring later in life due to in utero exposures. A report shall be developed to characterize the current approaches by EPA and other risk assessment organizations. Additionally, considering the unique data sets available for in utero exposure, reproductive, and developmental studies the report will explore the development of new risk assessment methodological approaches to adequately account for health effects reported within the study types listed in this task. The advantages and disadvantages of current and proposed future approaches shall be characterized in this report.

Specific requirements of this task:

- 7.1 Risk assessment approaches: The contractor shall develop a summary report characterizing current and possible future approaches for hazard identification and dose-response analysis for developmental, reproductive, and health effects resulting from in utero exposure.

Deliverable:

Summary report for current and future risk assessment methodologies for specific types of studies

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.d), *.out, *.opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3. Literature Search for Epi Literature from In Utero Exposures	
Task 3.1 – Literature Search and Hazard ID	
• Literature Search Product and Documentation	June 30, 2016
Task 4. Systematic Review	
Task 4.1 – Systematic Review and Dose-Response Analyses	
• Methods Report (including hypospadias pilot)	June 30, 2016
Asthma <ul style="list-style-type: none"> ○ Literature Search Result Summary ○ List of Studies and Chemicals ○ Data Extraction and Standardization ○ Summary Plots 	June 30, 2016 June 30, 2016 July 30, 2016 July 30, 2016
Cognitive Effects <ul style="list-style-type: none"> ○ Literature Search Result Summary ○ List of Studies and Chemicals ○ Data Extraction and Standardization ○ Summary Plots 	June 30, 2016 July 30, 2016 Within 2 weeks of Technical Direction Within 2 weeks of Technical Direction
Birth Outcomes <ul style="list-style-type: none"> ○ Literature Search Result Summary ○ List of Studies and Chemicals ○ Data Extraction and Standardization ○ Summary Plots 	July 15, 2016 July 15, 2016 August 15, 2016 August 15, 2016
Task 5. Efforts Related to Exposure Characterization	
Task 5.1 – Exposure Characterization	
• General Exposure Profiles for Selected Pollutants	June 30, 2016
• Exposure Characterization Publicly Available Biomarker Data	June 30, 2016
Task 6. Efforts related to AOPs	
Task 6.1 – AOP Evaluation and Analyses	
• Summary Report of Available Toxicological and Mechanistic Info for Selected Endpoint(s)	4 weeks from completion of Task 4
Task 7. Characterization of Risk Estimation Methodology and Potential Future Directions	
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• Summary report for current and future risk assessment methodologies for specific types of studies	

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Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

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Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

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After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

- 1.) Bibliographic identification of the study.

Study Identifiers:

Author(s):

Title:

Study Citation:

Storage location (e.g., library, facility archive, personal archive):

- 2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
- 3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
- 4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
- 5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
- 6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-47				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 2			Title of Work Assignment/SF Site Name TECHNICAL SUPPORT FOR NCCT PRO				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 11/12/2015 To 10/31/2016				
Comments: Specific Areas of Work, Section C (Risk Assessment Data Bases and Computer Tools, paragraph 1) and Section F (Information Management). Also relevant to this modification is Heading IV- Product Quality, Section B (Quality Assurance/Quality Control Requirements										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
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5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:			LOE:					
11/01/2013 To 10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name Matt Martin							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number 919-541-4104			
							FAX Number:			
Project Officer Name Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 703-347-8523			
							FAX Number: 703-347-8696			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name Adam Meier							Branch/Mail Code:			
_____ (Signature) (Date)							Phone Number: 513-487-2852			
							FAX Number: 513-487-2107			

**PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-47**

TITLE: TECHNICAL SUPPORT FOR NCCT PROFESSIONAL SERVICES

PERIOD OF PERFORMANCE: CO approval through 10/31/2016

I. PURPOSE

The purpose of this work assignment is to provide an independent review of the ToxCast database computer code for consistency and accuracy. This work falls under Heading III - Specific Areas of Work, Section C (Risk Assessment Data Bases and Computer Tools, paragraph 1) and Section F (Information Management). Also relevant to this modification is Heading IV- Product Quality, Section B (Quality Assurance/Quality Control Requirements) as it relates to ensuring that data generated are “of the type and quality needed and expected for their intended use.”

II. BACKGROUND

The National Center for Computational Toxicology (NCCT) of the U.S. Environmental Protection Agency’s (EPA’s) Office of Research and Development (ORD) is developing methods and models for screening large numbers of chemicals for biological activity and exposure. A major tool supporting this effort is the ToxCast data analysis pipeline. All information (raw and processed data, flags, model parameters, etc.) are stored in a relational database called InvitroDB. Final results are made available through the ToxCast dashboard which serves as the primary portal for publication and data release.

Critical to regulatory use as well as public acceptance of the data is that the analysis pipeline is viewed as scientifically accurate. In order to provide evidence of accuracy, an independent review of the results of the automated process is needed. The proposed project will take advantage of scientific expertise outside the Agency to provide an independent audit of the overall quality of the code contained in ToxCast.

III. STATEMENT OF WORK

Task: Review of ToxCast Database Computer Code

Step 1: The contractor will follow the provided instructions to download and install invitrodb_v1 and the tcpl R package locally, verifying that the documentation for this process is complete. This installation will require the use of MySQL and R on Windows 7, OS/X and Linux. Evaluators are expected to be proficient with installation and configuration of MySQL and R. In all cases, 64-bit versions will be used. Because the R-MySQL package can be problematic to install, brief instructions will be included.

Step 2: The contractor will perform the pipeline processing on one assay endpoint from each of the 7 data vendors, selected randomly. Instructions, including example code will be provided.

Step 3: Comment on level and clarity of documentation in the user manual (R package vignette), and function documentation provided with the tcpl R package.

Requirements for reviewer(s):

1. Reasonable experience with R programming and documentation, including R package structure and installing R packages from source in the Windows environment
2. Reasonable experience utilizing MySQL relational databases, including database installation (from a zip file) and database administration (updating permissions, changing database settings, etc.)

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**Work Assignment Number
2-47☐ Other ☐ Amendment Number:Contract Number
EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Title of Work Assignment/SF Site Name

Base Option Period Number 2

TECHNICAL SUPPORT FOR NCCT PRO

Contractor
ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/12/2015 To 10/31/2016

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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4										
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Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 Cost/Fee: \$0.00 LOE: 0

This Action: \$16,450.00 160

Total: \$16,450.00 160

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 12/02/2015 Cost/Fee \$16,450.00 LOE: 160

Cumulative Approved: Cost/Fee \$16,450.00 LOE: 160

Work Assignment Manager Name Matt Martin

Branch/Mail Code:

Phone Number: 919-541-4104

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

(Signature)

(Date)

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-48				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 2			Title of Work Assignment/SF Site Name HERO-DRAGON				
Contractor ICF INCORPORATED, L.L.C.						Specify Section and paragraph of Contract SOW Section IIIC: (Risk Assessment Databases and Compu				
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 11/01/2015 To 10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 11/01/2013 To 10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee: LOE:										
Cumulative Approved: Cost/Fee: LOE:										
Work Assignment Manager Name Connie Meacham <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number 919-541-3908 FAX Number: 919-541-5078			
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Adam Meier <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107			

PERFORMANCE WORK Statement
Contract EP-C-14-001
Work Assignment no. 2-48

Title: NCEA-HERO-DRAGON Interface & NCEA-HERO Support

SOW Section & Paragraph: Section IIIC: (Risk Assessment Databases and Computer Tools); Paragraph 1

Period of Performance: November 1, 2015 to October 31, 2016

I. Purpose

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) in the Office of Research and Development (ORD), in the National Center for Environmental Assessment (NCEA). Specifically, to provide services to support the NCEA Health and Environmental Research Online (HERO) database system, which is a tool used in developing Human Health Science Assessments and other NCEA documents.

II. Background

HERO is U.S. EPA National Center for Environmental Assessment (NCEA) application database system containing bibliographic references used in assessment development process. HERO currently includes nearly 3 million bibliographic references; ~80% are articles from peer-reviewed scientific research journals. There are several modules and tools within the NCEA HERO database system (e.g., LitSearch, Literature Import tools, LitBrowser tools [includes Project Pages, Tagging, LitFlow diagrams, Generation of Project-specific EndNote Libraries, and LitCiter], LitScreener, LitExtractor, LitReporter, etc.).

III. Statement of Work

A. Objective

The contractor shall perform various tasks for NCEA in support of the various projects and modules in HERO. The WAM, Connie Meacham, will give technical direction on the support tasks.

The tasks involve:

- Continuing to develop a HERO-DRAGON interface (web services API), and a series of other (intermediary) methods of electronic transfer of information collected for NCEA in the ICF DRAGON tool (i.e., literature screening data, modeling data, extracted data, and formatted DRAGON output) into HERO.
- Data cleaning and quality control of information on at least 10 different HERO Project Pages and any associated LitFlow Diagrams associated with various programs within NCEA (such as ISAs, IRIS Toxicological Reviews, PPRTVs, and Other high-profile projects).

The WAM will provide prompt feedback to the contractor on the acceptability and performance of the tasks.

B. Specific Requirements

Task 1: Submit Work Plan to reflect the continuation of WA 1-48.

Task 2: Develop a HERO-DRAGON interface (web services API), and a series of other (intermediary) methods of electronic transfer of modeling data, screening data, and extracted data from DRAGON into HERO. Additional alternate methods of phased electronic data transfer will be necessary to move this

task forward toward the completion of the API. Once the API is in place, all the data collected for NCEA into the DRAGON MS Access databases, the DRAGON MySQL database, and into the DRAGON OnLine tool shall be exported by ICF and imported into the NCEA HERO database system on a regular ongoing basis.

Skills needed: Understanding of web services API (Application Programming Interface), Microsoft Office (MS) Access Databases, MS Excel Spreadsheets, xml format, JSON Objects, JAVA, Word Tables, MySQL databases, NoSQL databases, and DRAGON processes (literature screening, DRAGONScreen, data extraction / fact extraction) and DRAGON queries and output formats.

Task 3: Data cleaning and quality control of information on various HERO Project Pages and LitFlow diagrams.

EPA will provide the EPA Portal accounts and HERO tools and permissions as necessary.

Skills needed: Attention to detail, understanding of bibliographic reference data, a thorough understanding of HERO applications and EPA user environment, technical writing skills, an understanding of the assessment development process.

The WAM will assign the projects for which the bibliographic references shall be checked for completeness and accuracy. Each project shall be checked for appropriateness of the “tag tree” associated with the project on the Project Page and the LitFlow diagram. This “tag tree” checking may involve the EPA chemical (project expert/assessment manager) manager of the project as well as the WAM. The contractors shall enter corrections directly in the HERO database using the HERO web interface or send importable data to the HERO Technical Lead.

IV. Deliverables

All deliverables will be electronic.

All technical directions will be given via email.

Email will be used to communicate with the contractor.

Notice Regarding Guidance Provided under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

V. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment.

Periodic meetings (generally once every week, or once every 2 weeks if there are scheduling conflicts) between the EPA WAM and contractor staff shall be necessary to discuss questions that may arise during performance or completion of this work assignment. At the EPA WAM’s discretion, these meetings may occur via teleconference or webinar. The contractor shall document these meetings and submit copies of this documentation to the EPA WAM.

Travel: No Travel is expected to occur during the course of this work assignment.

Green Meetings: No in-person meetings are expected to occur during the course of this work assignment.

For ICF Work Assignments from NCEA that have “Data Extraction” or “Evidence Tables” or “Systematic Review” or “DRAGON-SCREEN” or “DRAGON” or “DRAGON-ONLINE” as part of the task(s) in the Work Assignment.

In addition to the deliverables in this Work Assignment, ICF shall export data extracted for EPA (as part of this Work Assignment) to the NCEA HERO Database System (either by an API* or machine readable data files [if the API* is not ready], which can be automatically imported into the NCEA HERO Database System).”

*Definition of API: Application Program Interface - - a software intermediary that allows computer applications or systems to automatically interact with each other to share data.

VI. EPA Contact Information

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO (Melissa Revely-Wilson; revely-wilson.melissa@epa.gov).

Work Assignment Manager (WAM)

Connie A. Meacham, M.S. (Biologist)
HERO Project Lead
U.S. EPA, NCEA-RTP
109 TW Alexander Drive, Mail Drop B243-01
Research Triangle Park, NC 27711
Telephone: (919) 541- 3908
Cell: (919) 369-8600
meacham.connie@epa.gov

Packages/Courier Address:

Connie Meacham
U.S. EPA MD B243-01
4930 Old Page Road
Durham, NC 27703

Alternative Work Assignment Manager (Alt-WAM)

Ryan Jones, M.S. (Information Specialist)
HERO Technical Lead
U.S. EPA, NCEA-RTP
109 TW Alexander Drive, Mail Drop B243-01
Research Triangle Park, NC 27711
Telephone: (919) 541- 9415
Fax: (919) 541- 5078
jones.ryan@epa.gov

Packages/Courier Address:

Ryan Jones
U.S. EPA MD B243-01
4930 Old Page Road
Durham, NC 27703

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-48				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 2			Title of Work Assignment/SF Site Name -HERO Support				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW Section IIIC					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval						Period of Performance From 11/01/2015 To 10/31/2016				
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee: \$0.00				LOE: 0				
11/01/2013 To 10/31/2016										
This Action:		\$245,898.00				3,817				
Total:		\$245,898.00				3,817				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: 11/20/2015		Cost/Fee: \$245,898.00				LOE: 3,817				
Cumulative Approved:		Cost/Fee: \$245,898.00				LOE: 3,817				
Work Assignment Manager Name Connie Meacham <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 919-541-3908 FAX Number: 919-541-5078				
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:				
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name Adam Meier <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107				

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-49				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 1			Title of Work Assignment/SF Site Name Ethylene Oxide				
Contractor ICF INCORPORATED, L.L.C.						Specify Section and paragraph of Contract SOW A.1,2,4 and B.1,2,5				
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 11/06/2015 To 10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
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Authorized Work Assignment Ceiling										
Contract Period: Cost/Fee: LOE: 11/01/2013 To 10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: Cost/Fee: LOE:										
Cumulative Approved: Cost/Fee: LOE:										
Work Assignment Manager Name John Fox <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number 703-347-8598 FAX Number:			
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name Adam Meier <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107			

**PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-49**

TITLE: Ethylene Oxide - Epidemiology Modeling and Exposure Characterization

Principal Section & Paragraph of SOW: A.1,2,4 and B.1,2,5

PERIOD OF PERFORMANCE: CO Issuance – October 31, 2016

I. PURPOSE

This work assignment is a continuation of WA 1-49. The purpose of the work assignment is to provide services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of a carcinogenicity assessment for Ethylene Oxide. Specifically, this work assignment will provide exposure-response modeling using NIOSH cohort study data, and characterizations of exposure levels estimated for jobs and locations pertinent to the cohort study.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Task 1: Work Plan and Quality Assurance Project Plan (QAPP)

The contractor shall prepare a Work Plan and a Quality Assurance Project Plan (QAPP). The Work Plan shall state that the QAPP will be observed during the conduct of this work assignment. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP

Due Date: 15 days after issuance of this Performance Work Statement (PWS).

Task 2. Exposure-Response Modeling of NIOSH Mortality Cohort Study Data and Exposure Characterization

Exposure-response modeling was conducted for the Ethylene Oxide ("EtO") assessment prior to SAB review. The SAB requested further analyses. These were addressed under WA 1-49. This task provides for a limited LOE of no more than 40 hours for revising or amending work done under WA 1-49, including:

- a. exposure-response modeling of the lymphoid cancer mortality data in the NIOSH cohort study, including sensitivity analyses of various models and model features (such as knot choices, age-exposure interactions)
- b. characterization of the exposure distributions in the cohort and their changes over time
- c. analysis of selected characteristics of the cohort
- d. consultation with EPA on working with the cohort study data and review of analyses that can be conducted by EPA staff
- e. addressing specific SAB comments about the exposure-response modeling:
 - i. discuss the extent to which the NIOSH study results are consistent with results from the Union Carbide Cohort study and the Mikoczy et al. (2011) study
 - ii. put the extra lifetime risk in terms of the number of lymphoid cancers that are due to exposure to EtO in the cohort
- f. examination and characterization of exposure levels in relation to jobs, locations and time

Deliverables: To be specified in written technical direction

Due Dates: To be specified in written technical direction

Task 3: Consultation with EPA staff and assistance with responses to SAB comments

This task provides for a limited quantity of assistance with explaining, and executing data analyses and writing or reviewing draft responses to the SAB comments. The Task is expected to require less than 40 hours.

- a. consultation with EPA on working with the cohort study data and review of analyses that can be conducted by EPA staff
- b. assistance in responding to SAB comments about the exposure-response modeling; review of selected responses

Deliverables: To be specified in written technical direction

Due Dates: To be specified in written technical direction

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	Schedule (all days are elapsed calendar days unless otherwise stated)
1. Work Plan and Quality Assurance Project Plan	15 days after receipt of this PWS
2. Exposure-Response Modeling of NIOSH Cohort Study Data and Exposure Characterization	To be specified in written technical direction
3. Consultation with EPA staff and assistance with responses to SAB comments	To be specified in written technical direction

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Project Officer (PO)

Melissa Revely-Wilson, Acquisition Specialist
Office of Research and Development (8601-P)
Office of Administrative and Research Support
Extramural Management Division - Contracts Branch
Telephone: 703/347-8523 (AWL 540/891-6405) Fax: 703/347-8696
Revely-Wilson.Melissa@epa.gov

Mailing Address:

National Center for Environmental Assessment
Office of Research and Development (8623-P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Physical Address:

U.S. Environmental Protection Agency
Two Potomac Yard (North Building),
2733 S. Crystal Drive, Arlington, VA 22202

EPA Work Assignment Manager (WAM)

John Fox
703-347- 8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov

Mailing Address:

U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P)
1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:

U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment
Two Potomac Yard North, 7th Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

Technical Advisor (Not a WAM/or COTR)

Jennifer Jinot (Assessment Manager for Ethylene Oxide; EPA Statistician)
703-347-8597 jinot.jennifer@epa.gov

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-49

☐ Other ☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base

Option Period Number

2

Title of Work Assignment/SF Site Name

Ethylene Oxide

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

A.1,2,4 and B.1,2,5

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/06/2015 To 10/31/2016

Comments:

☐ Superfund

Accounting and Appropriations Data

☒ Non-Superfund

SFO

(Max 2)



Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

Cost/Fee: \$0.00

LOE: 0

11/01/2013 To 10/31/2016

This Action:

\$23,163.00

82

Total:

\$23,163.00

82

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

11/30/2015

Cost/Fee

\$23,163.00

LOE: 82

Cumulative Approved:

Cost/Fee

\$23,163.00

LOE: 82

Work Assignment Manager Name John Fox

Branch/Mail Code:

Phone Number: 703-347-8598

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

(Signature)

(Date)

FAX Number:

Contracting Official Name

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

(Signature)

(Date)

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-50			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001		Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 2		Title of Work Assignment/SF Site Name EPA-Eco-Box					
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW III. C					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 11/01/2015 To 10/31/2016			
Comments:									
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO <input type="checkbox"/> (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		LOE:					
11/01/2013 To 10/31/2016									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee:		LOE:			
Cumulative Approved:				Cost/Fee:		LOE:			
Work Assignment Manager Name Linda Phillips <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number 703-347-0366			
						FAX Number:			
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number: 703-347-8523			
						FAX Number: 703-347-8696			
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number:			
						FAX Number:			
Contracting Official Name Adam Meier <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number: 513-487-2852			
						FAX Number: 513-487-2107			

**PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-50**

TITLE: Technical Support for Development of EPA-Eco-Box (a toolbox for ecological risk assessors)

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2016.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for the continued development of EPA-Eco-Box (a toolbox for ecological risk assessors).

II. BACKGROUND AND OBJECTIVES.

EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) is developing EPA-Eco-Box as a web-based compendium of tools used in ecological risk assessment. It will be comprised of a series of Tool Sets, each containing modules that address topics in ecological risk assessment. Each toolbox module will contain a description of the topic and links to ecological risk assessment resources that address that topic, including databases, models, guidance documents, and other relevant tools. A search interface will allow users to identify resources using keywords or topics. Technical assistance will be required for completing the development of EPA-Eco-Box that began under work assignment 1-50 of this contract. This will include: developing/finalizing Tool Set module content, populating the Master Tool List, and addressing comments received from EPA-Eco-Box reviewers and assisting with modifications or revisions, as needed. Development of the website to house EPA-Eco-Box is not included in this work assignment.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of four tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall assist in developing/finalizing the content for EPA-Eco-Box Tool Sets and modules.

The contractor shall develop/finalize content for EPA-Eco-Box. This shall include brief introductory text for each of the Tool Sets, as well as text and tool lists for each of the modules. Module content may also include graphics, photo images, or other types of reference materials, as needed to convey concepts of ecological risk assessment, as described in relevant EPA guidance documents. The draft revised content for each of the Tool Sets shall be submitted to the COR **within 3 weeks of receiving technical direction from the COR**. The contractor shall submit final content **within 2 weeks of receiving comments on the draft content from the COR**.

Deliverable 2a: The contractor shall submit draft revised Tool Set and module content **within 3 weeks after being notified by the COR that they should begin work**.

Deliverable 2b: The contractor shall submit final Tool Set and module content **within 2 weeks of receiving comments on the draft content from the COR**.

Task 3. The contractor shall finalize/revise the Master Tool List for EPA-Eco-Box.

The contractor began development of a Master Tool List for EPA-Eco-Box under work assignment 1-50 of this contract. Its purpose is to provide a comprehensive listing of all the tools included in the toolbox, and will be used to:

- (1) populate tables within each of the Tool Set modules with tools relevant to that topic area; and
- (2) allow the toolbox to be searched using key words.

This Master Tool List will need to be finalized before EPA-Eco-Box can be deployed. It may also need to be revised, as needed, based on reviewer comments or to add new or revised tools that become available or are identified after EPA-Eco-Box's initial development. The contractor shall finalize or revise the Master Tool list for EPA-Eco-Box. The contractor shall provide a listing of all tools to be included in EPA-Eco-Box along with a brief description, URL, and relevant key words.

The contractor shall provide the necessary information to revise and update the Master Tool List, as needed, to incorporate any new tools that have been identified from comments on the Toolbox, to add tools based on the revision of existing content or to add new or revised tools. The contractor shall also provide the necessary information to correct broken links in the Toolbox after deployment. The contractor shall also ensure that any new or updated tools have been appropriately assigned to the various Tool Sets, modules, and sub-modules (many of the tools will be applicable in more than one module or sub-module), and that accurate tool descriptions and key words are provided. The contractor shall submit all of the draft information necessary to revise and update the Master Tool List to the COR **within 2 weeks after of receiving a written request from the COR**. **Within 1 week after receiving comments from the COR**, the contractor shall submit the final information necessary to update the Master Tool List.

Deliverable 3a: The contractor shall submit to the COR draft information necessary to revise and update the Master Tool List **within 2 weeks of receiving a written request from the COR.**

Deliverable 3b: The contractor shall submit the final information necessary to update the Master Tool List to the COR **within 1 week after the receipt of the COR's comments on Deliverable 3a.**

Task 4. The contractor shall assist in addressing comments on EPA-Eco-Box.

The contractor shall assist EPA in reviewing any comments received on EPA-Eco-Box, and formulating plans for addressing these comments. **Within 1 week after receiving comments from the COR,** the contractor shall arrange a conference call with the COR to discuss the comments and the next steps for making revisions to the Toolbox. The contractor shall prepare and submit to the COR draft responses **within 2 weeks of the COR assigning issues or topic areas** that will need to be addressed. For the purpose of preparing the work plan and cost estimate for this work assignment, the contractor shall assume that there are 5 key issues to be addressed, and that any other comments will require only minor revisions. The list of comments and their resolution shall be maintained in order to track revisions made to the Toolbox. This list will include key issues as well as other minor corrections.

Deliverable 4a: The contractor shall arrange a conference call with the COR **within 1 week after the receiving comments from the COR.**

Deliverable 4b: The contractor shall prepare responses to the issues **within 2 weeks of being assigned by the COR.**

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a	Establish communication via conference call	Within 1 week after receipt of work assignment
2a	Submit draft revised Tool Set content	Within 3 weeks of being assigned by COR
2b	Submit final Tool Set content	Within 2 weeks of receiving comments on outline from EPA COR
3a	Submit draft update to Master Tool List	Within 2 weeks of receiving written request from COR
3b	Submit final update to Master Tool List	Within 1 week of COR comments
4a	Arrange conference call	Within 1 week of receiving comments from COR
4b	Prepare comment responses	Within 2 weeks of being assigned by COR

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager Linda Phillips US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-0366 FAX #: (703) 347-8690 Email: phillips.linda@epa.gov	Alternate WAM Jacqueline Moya US EPA (8623P) National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-8539 FAX #: (703) 347-8694 Email: moya.jacqueline@epa.gov
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EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 2-50				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base Option Period Number 2			Title of Work Assignment/SF Site Name EPA-Eco-Box				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW III.C					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval						Period of Performance From 11/01/2015 To 10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		\$0.00		LOE:		0		
11/01/2013 To 10/31/2016										
This Action:				\$39,154.00				429		
Total:				\$39,154.00				429		
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		11/19/2015		Cost/Fee:		\$39,154.00		LOE:		429
Cumulative Approved:				Cost/Fee:		\$39,154.00		LOE:		429
Work Assignment Manager Name Linda Phillips <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
						Phone Number 703-347-0366				
						FAX Number:				
Project Officer Name Melissa Revely-Wilson <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 919-541-0207				
						FAX Number:				
Other Agency Official Name <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
						Phone Number:				
						FAX Number:				
Contracting Official Name Adam Meier <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>						Branch/Mail Code:				
						Phone Number: 513-487-2852				
						FAX Number: 513-487-2107				